K033080

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smiths

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H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Cynthia Engelhardt
Technical Writer, Regulatory Affairs

PREPARATION DATE OF SUMMARY:

March 9th, 2004

TRADE NAME:

Portex® 24g Pediatric Epidural and Peripheral Block Anesthesia Catheter

COMMON NAME:

Anesthesia Conduction Catheter

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 BSO, 21 CFR 868.5120

PREDICATE DEVICE(S):

Predicate 1: The B. Braun Periflex Continuous Epidural Pediatric Tray, K962696.
This is the main predicate device cited for catheter size, design characteristics and indication for use.

Predicate 2: Our current 16g and 18g Epidural Catheter kits, K992471.
This predicate device is cited, in conjunction with Predicate 1 above for materials, biocompatibility, sterilization and packaging.

Predicate 3: Our 23g Pediatric Epidural Minipack, K924541.
This predicate device is cited, in conjunction with Predicate 1 above for tensile strength and elongation.

Predicate 4: Our 21g High Durometer Epidural; Catheter, K935927.
This predicate device is cited, in conjunction with Predicate 2 above for biocompatibility for the ink.

DESCRIPTION:

The Portex® 24g Pediatric Epidural and Peripheral Block Anesthesia Catheter is made of flexible, nylon tubing. The catheter is open-ended catheter with finished tip. The tip of the catheter is marked. The catheter has a single mark at 5 cm from the tip with 1 cm increments, up to 20 cm. The 10 cm mark is indicated by two marks, 15 cm by three marks, and 20 cm by four marks.

The catheter is available in 24g (O.D. 0.022"/I.D. 0.012") size. The catheters have a nominal length of 36 inches. The catheter includes a stylet.

The catheters are provided with a catheter connector to provide a means of administration of anesthetics and/or analgesics. They are provided sterile as a component of a continuous anesthesia conduction catheter mini tray.

INDICATIONS FOR USE:

The Portex® 24g Pediatric Epidural and Peripheral Block Anesthesia Catheter is designed for use primarily in pediatric applications (children under 12 years, infants and neonates) for continuous or intermittent regional anesthesia, e.g. epidural, caudal and peripheral blocks. The duration of use should not exceed 72 hours.

TECHNICAL CHARACTERISTICS:

The design of the proposed catheter is similar to predicate 1 marketed under premarket notification K962696 by B. Braun and predicate 3 that we have authorization to market under premarket notification K924541 . The catheter material is identical to predicate 2 that we have authorization to market under premarket notification K965017. The ink is identical to predicate 4 that we have authorization to market under premarket notification K935927. The technical characteristics of the characteristics fall within the values of the predicate Portex catheters and the B. Braun catheter.

NON-CLINICAL DATA:

Data submitted demonstrates that the anesthesia conduction catheter performs equivalently to the predicate devices. Data submitted covers; dimensional characteristics, flow rate, compression resistance, hub/catheter detachment, deflection resistance modulus of elasticity, tensile strength, and elongation.

CLINICAL DATA:

Not applicable

CONCLUSION:

The comparison to the predicate devices demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Cynthia Engelhardt
Technical Writer, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2004

Ms. Cindy Engelhardt
Regulatory Affairs/Technical Writer
Portex Incorporated
10 Bowman Drive
Keene, NH 03431

Re: K033080
Trade Name: Portex 24g Pediatric Epidural and Peripheral Block Anesthesia Catheter
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthetic Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: February 18, 2004
Received: February 19, 2004

Dear Ms. Engelhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

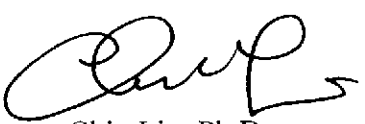
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033080

Device Name: Portex® 24g Pediatric Epidural and Peripheral Block Anesthesia Catheter

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Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033080